Nursing Management of Patients Requiring Acute Mechanical Circulatory Support Devices

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Historically, most patients in cardiac care units (CCUs) have been admitted with the diagnosis of acute myocardial infarction (AMI) or a complication of AMI. As technologies for percutaneous coronary intervention (PCI) and implementation of early treatment for AMI have improved, the in-hospital mortality rate for AMI has declined to less than 10% and the number of patients surviving to hospital discharge has increased. Despite timely reperfusion, however, between 40% and 70% of patients with AMI subsequently develop heart failure within 5 years after discharge. Thus, the number of patients with heart failure has grown to more than 8 million in the United States alone, and CCUs are now managing more patients with acute heart failure and cardiogenic shock. A central aspect of CCU management for heart failure and cardiogenic shock is the use of acute mechanical circulatory support...
Benefits of the IABP include an increase in coronary and cerebral perfusion pressure during inflation, a decrease in workload and oxygen consumption during deflation, and an increase in CO.

Indications

The IABP is recommended for short-term use in the management of cardiogenic shock, refractory unstable angina, or refractory or intractable ventricular tachycardia; supporting preoperative or postoperative cardiac surgery; or as a bridge to advanced therapies (ventricular assist device [VAD] or transplant). Additional indications include acute mitral regurgitation due to papillary rupture, ventricular septal rupture, as an adjunct to other VADs, and after failed PCI. The IABP should not be used in patients with aortic dissection, significant aortic regurgitation, or thoracic aneurysms. Whether the IABP is still recommended for cardiogenic shock is currently under debate. Contemporary European guidelines identify IABP therapy as not routinely indicated and potentially harmful (class III recommendation) in cardiogenic shock.

Mechanics

Counterpulsation is the fundamental principle underlying the IABP. During diastole, the IABP inflates and displaces blood from the descending aorta while increasing diastolic pressure in the aortic root. During systole, the IABP deflates, creating a negative pressure sink in the descending aorta that reduces cardiac afterload and increases LV stroke volume. The preferred gas with which to inflate the catheter is helium because of its low molecular weight and the ability to shuttle the gas back and forth at a high speed. Accurate timing is essential to ensure that patients receive the intended hemodynamic benefits. These benefits can include an increase in coronary and cerebral perfusion pressure during inflation, a decrease in workload and oxygen consumption during deflation, and an increase in CO of about 0.5 L/min.

Catheters vary in size, and the percentage of augmentation rises with balloon size. The IABP has 3 settings (1:1, 1:2, or 1:3), indicating the ratio of heartbeats to balloon inflations. On full IABP support, the nurse will see a 1:1 ratio, providing 3 times the number of balloon inflations as at the 1:3 setting, which may be used when weaning a patient off of IABP therapy.

The most common access site for the IABP is the femoral artery; however, axillary implantation is occurring more frequently to allow for early ambulation. The IABP can also be placed using a transthoracic approach in the setting of cardiac surgery. This application offers a lower
risk of lower-extremity ischemia but may be associated with a higher risk of sternal infections and neuroembolic events.\textsuperscript{13,14}

**Nursing Considerations**

Nursing care of the patient with an IABP focuses on confirming accurate timing, preventing complications, and troubleshooting alarms from consoles. Exact timing is based on appropriate inflation and deflation of the balloon during the cardiac cycle. The consoles have an automatic mode, which determines inflation and deflation points, but occasionally the critical care nurse may need to use the semiautomatic mode to choose inflation or deflation points in order to maximize hemodynamic effects. When looking at the IABP waveform, the nurse should see inflation occur at the dicrotic notch, which...
represents the onset of diastole, and deflation should occur before the next systole.\textsuperscript{5,7,8,12} Inflation is triggered automatically by the R wave of the electrocardiogram. If the patient does not have a reliable R wave (low-voltage electrocardiogram, electrocautery interference, and 100% paced), a pressure trigger can be selected instead. For patients with a fast or irregular heart rate, the nurse will need to assess which trigger is most effective.\textsuperscript{11}

Monitoring the augmentation and unloading effects of the device along with the patient’s vital signs and urine output every hour is critical.\textsuperscript{7} Changes may indicate a timing error, poor tolerance of weaning, or perhaps catheter migration below the renal artery if urine output decreases.

Complications associated with counterpulsation include distal-extremity ischemia secondary to obstruction of
blood flow due to catheter size, vascular damage, bleeding, thrombus formation, catheter rupture, infection, catheter migration, and hazards associated with prolonged immobility. The left radial pulse must be monitored to ensure that the catheter has not migrated across the aortic arch, which would obstruct the left subclavian artery, potentially causing a stroke due to blood flow obstruction. The catheter should be assessed frequently for possible leaks or perforations, which would increase the risk of arterial air emboli.

**TandemHeart**

The TandemHeart system (LivaNova) is a percutaneously implanted extracorporeal centrifugal-flow pump designed to deliver up to 5 L of flow to replace a patient’s CO. This device establishes a left atrium (LA)-to-femoral artery bypass, which unloads the LV by its preload. The TandemHeart pump can also be configured for right ventricular (RV) failure by employing a right atrial (RA)-to-pulmonary artery (PA) bypass circuit using the single Protek-Duo cannula.

**Indications**

The TandemHeart is indicated for high-risk PCI and cardiogenic shock. When used to support LV function, the device decreases LV volume and stroke work, pulmonary artery occlusion pressure (PAOP), and myocardial oxygen consumption while increasing mean arterial pressure, mixed venous oxygen saturation, and organ perfusion. The device may work as a bridge to recovery, durable VAD implantation, or heart transplant. This device is contraindicated in patients who have left or right atrial thrombus.

**Mechanics**

A 21-French cannula is placed via the right femoral vein into the inferior vena cava and advanced through the RA to the LA through a transseptal puncture. Oxygenated blood is pulled out of the LA and pumped back into the arterial circulation through a percutaneously placed cannula in a femoral artery. A heparinized saline solution runs continuously through the console to the pump head to promote lubrication and cooling and
decrease clot formation within the pump chamber. When used as an RV support device, the Protek-Duo cannula is placed in the right internal jugular vein (RIJV), pulls blood from the RA, and returns to the PA, thereby bypassing the RV.5,11

Nursing Considerations

As with all AMCS devices, patients being managed on the TandemHeart pump are preload dependent and need careful monitoring of intravascular volume status.20 If a drop in flow is noted, first the cannulas should be assessed for any kinks, and then the patient’s volume status and cardiac filling pressures should be evaluated. The nurse can perform this evaluation at the bedside by monitoring central venous pressures with a central venous catheter or by monitoring RA pressures and PAOP with a PA catheter. Cardiac filling pressures can also be estimated by clinical assessment and by echocardiogram. Arrhythmias, which decrease stroke volume, can also cause a drop in flows, as well as RV dysfunction and pulmonary hypertension.36 Patients with the LV support configuration have an increased risk of cardiac tamponade, as placement of the device required a transseptal puncture.11 Furthermore, all intravenous fluids running through a central catheter should have a filtering mechanism to prevent delivery of an air embolus. If air was not filtered out, it could enter the arterial system through the transseptal puncture and cause a stroke due to paradoxical air embolism. Mean arterial pressures should be monitored in these patients, as their arterial waveforms may be nonpulsatile because of reduced LV systolic ejection.11,16

During femoral cannulation, the insertion side leg should be immobilized to avoid cannula kinking or accidental advancement or removal. The cannula insertion site should be closely monitored, as cannula dislodgment is a life-threatening complication. Daily chest radiographs and echocardiograms are needed to confirm cannula position. In the LV configuration, if the cannula retracts across the intra-atrial septum, the nurse would see rapid arterial oxygen desaturation, as the retraction would cause a right-to-left shunt.5,11,16 If a retraction occurred, flows would need to be decreased and immediate imaging obtained to reposition the cannula. If in the RV support configuration the Protek-Duo migrates forward into a PA branch, the patient will show signs and symptoms of respiratory failure, such as tachypnea and oxygen desaturation. If the cannula is pulled back into the RV, CO will drop, tricuspid regurgitation will be present, and arrhythmias may occur.5,13,16

Impella

The Impella platform of AMCS devices (Abiomed) includes 4 axial-flow catheters. Three of these are designed as LV support devices with varying sizes and applications, and the fourth is designed to assist in RV failure. Combinations of these devices have also been used to provide biventricular support.17

Indications

The Impella 2.5, Impella CP, and Impella 5.0/LD catheters are the only AMCS devices approved by the US Food and Drug Administration for the treatment of cardiogenic shock that is refractory to medical management. The Impella 2.5, CP, and 5.0 systems are also used for high-risk PCI or electrophysiology procedures.18,19 The Impella RP is indicated for circulatory assistance of up to 14 days in patients who develop acute right-sided heart failure or decompensation after left VAD implantation, myocardial infarction, heart transplant, or open heart surgery.20

Contraindications to selecting Impella support may include LV thrombus, mechanical aortic valves, aortic valve insufficiency, tortuous iliac artery or vessel or anatomical disorders precluding placement or correct positioning, LV rupture, or tamponade.18 Specific contraindications to the RP device include any PA disorders.20

Mechanics

The Impella devices are minimally invasive, catheter-mounted, microaxial-flow pumps.18 An axial pump is composed of impeller blades, or rotors, that spin around a central shaft and move blood through the device. The Impella 2.5 (12 French), Impella CP (14 French), and Impella 5.0/LD (21 French) offer up to 2.5 L, 3.5 L, and 5 L of flow, respectively.13 The Impella works by directly unloading the LV. Seated across the aortic valve, the catheter pulls blood from the LV and pumps it into the ascending aorta, reducing myocardial workload and oxygen consumption while increasing CO and coronary and end-organ perfusion.18 The Impella 2.5 and CP pumps can be inserted percutaneously into the femoral or axillary artery. The Impella 5.0 requires a surgical cutdown of either the axillary or the femoral artery. Given the higher magnitude of Impella 5.0 flow, this device is often
favored over the 2.5 or CP devices for patients with advanced heart failure requiring prolonged support.\textsuperscript{21} Axillary insertions allow for the option of mobilizing the patient, which can be critical for surgical optimization if the patient needs a bridge to a durable VAD or to transplant.\textsuperscript{11,22} The Impella LD can be surgically inserted directly into the aorta during open heart surgery, often when a patient is unable to come off of bypass because of LV failure. With the Impella RP, a 22-French catheter is inserted into a femoral vein, removing blood from the inferior vena cava and pumping it into the PA to unload the RV.\textsuperscript{20}

**Nursing Considerations**

Each of the Impella catheters is controlled by an Automated Impella Controller (AIC) that displays flow rate, performance (P) level, purge fluid rate, purge fluid pressure, alarm notes, and catheter position information. Many nursing considerations for the Impella devices involve monitoring these parameters.\textsuperscript{18}

The placement waveform and the motor current are derived from 2 different pressure readings on the Impella catheter, which help determine the location of the Impella and can trigger placement alarms. On all Impella devices, the nurse should always ensure that the motor current waveform is pulsatile, which indicates proper position and function. If alarms suggest malpositioning, the nurse should alert the physician and expect an echocardiogram to be obtained, as it is the best indicator of positioning, as well as a chest radiograph.\textsuperscript{18}

With the Impella 2.5 and CP, the placement waveform should look like an aortic waveform; however, it does not provide accurate blood pressure measurements and cannot be used as a replacement for arterial pressure monitoring. If the placement waveform looks like an LV waveform, the catheter has likely migrated forward too far into the LV. If the devices were pulled back entirely into the aorta, there would be little difference in the placement waveform, but there would be a malpositioning alarm, most likely paired with a change in patient status.\textsuperscript{18}

With the Impella 5.0 and LD, the nurse will not see a ventricular or an aortic waveform as with the 2.5 or CP but should expect to see a pulsatile waveform on the AIC. A flattened waveform would indicate that the catheter is either entirely in the ventricle or in the aorta and not correctly placed across the aortic valve. This pulsatile waveform reflects the catheter’s pressure difference between its internal sensor, which should reflect ventricular pressure, and its external sensor, which should reflect aortic pressure.\textsuperscript{18}

In patients with low native heart pulsatility, the placement may be difficult to determine on the basis of the waveforms and pressure readings alone, and the AIC will indicate that the position is unknown. To prevent malposition, care should be taken to document the number marking on the catheter at the insertion site, the catheter should be sutured securely in place, and knee immobilizers should be used if the catheter is inserted femorally.\textsuperscript{18}

The AIC controls the entire purge line and maintains adequate purge pressure between 300 and 1050 mm Hg to prevent blood from compromising the motor.\textsuperscript{18} The nurse must change the purge fluid bag and change the purge fluid tubing, cassette, and pressure tubing per hospital policy. The recommended purge solution is 5% dextrose in water with 50 units/mL of heparin.\textsuperscript{18} The dosage of heparin that the AIC delivers through the Impella catheter to the patient is displayed hourly and must be documented.

Patients may be receiving a combination of heparin delivered through the Impella and peripherally to achieve an anticoagulation goal. After insertion, an activated clotting time goal of 160 to 180 seconds is recommended while the catheter is implanted, but nurses can expect their institutions to implement weight-based partial thromboplastin time or anti-Xa protocols as well.\textsuperscript{18} Special consideration is required when using 2 different Impella catheters at the same time (eg, RP and 5.0). Because of the use of 2 separate purge systems, the heparin concentration of each bag should be carefully evaluated to prevent larger doses of heparin from being unintentionally administered to the patient.

Because all AMCS devices are preload dependent, suction alarms may occur when a patient is in a low-volume state. If filling pressures are adequate, catheter malposition or, in left VADs, RV failure may be the cause. In most cases, when the patient is receiving full Impella support, a target PAOP of 10 to 15 mm Hg should provide adequate device preload. The nurse

**The Impella directly unloads the left ventricle as it is seated across the aortic valve, pulling blood from the left ventricle and pumping it to the aorta.**
should anticipate turning down the P level while potential causes are being evaluated. Another reason to turn down the P level would be if cardiopulmonary resuscitation (CPR) is required. The P level can be increased again as tolerated with return of spontaneous circulation. The nurse should assess the device’s placement signals and anticipate a chest radiograph and echocardiogram to confirm placement after compressions.

Hemolysis is a risk when patients have these mechanical support devices, as blood cells may become damaged while going through the pump. Hemolysis is often due to improper position of the pump, low preload, or prolonged use of a high speed setting in the case of the Impella 2.5 or CP device. Hemolysis is less common with the Impella 5.0 pump. Clinical signs may include dark or bloody urine, low hemoglobin level, and renal failure. While the patient is using the support device, the nurse should monitor the plasma-free hemoglobin level, which is the best indicator of hemolysis.

**Extracorporeal Membrane Oxygenation**

Extracorporeal membrane oxygenation (ECMO) is a modified cardiopulmonary bypass circuit that uses a centrifugal-flow pump. Patients are considered for ECMO in the setting of cardiac and/or respiratory failure when the process is potentially reversible and the risk of mortality is high. Through a variety of cannulation configurations, patients are supported on either venoarterial (VA) ECMO or venovenous (VV) ECMO.

Although all ECMO patients require a perfusionist or an ECMO specialist (a specially trained registered respiratory therapist or registered nurse) at the bedside at all times, the critical care nurse should be aware of indications, mechanics, and specific considerations in caring for these patients.

**Venoarterial Indications**

Venoarterial ECMO is indicated in adult patients who require hemodynamic support as well as respiratory support in the setting of a potentially reversible cause of heart failure. It is most often used for patients with persistent cardiopulmonary failure that is refractory to conventional therapies such as volume resuscitation, inotropes, vasopressors, and other AMCS devices. As VA ECMO bypasses the native heart and lungs, it can provide close to 60% to 80% of the patient’s resting CO. In some medical facilities, septic shock can also be an indication for ECMO. Contraindications to VA ECMO include an unrecoverable heart in patients who are not VAD or transplant candidates, multisystem organ failure, anoxic brain injury, or known intraventricular hemorrhage.

**Venoarterial Mechanics**

A VA ECMO circuit is composed of a cannula placed in a vein to drain deoxygenated blood from a patient, which is then drawn into the ECMO circuit by a centrifugal-flow pump. The blood then passes through a membrane oxygenator that removes carbon dioxide and adds oxygen and then finally delivers oxygenated blood back to the patient through a cannula placed in an artery. Pump flow and sweep gas flow can be adjusted by the ECMO specialist to augment hemodynamics, oxygenation, and gas exchange. Adults can be cannulated peripherally, generally in the femoral sites, or patients can be surgically (centrally) cannulated through the RA and aorta. A potential benefit of central cannulation is that the patient can ambulate.

**Venoarterial Nursing Considerations**

The critical care nurse should be aware of specific considerations when monitoring a patient receiving VA ECMO. Because it is a nonpulsatile system, the nurse can expect to see a decrease in a patient’s native pulsatility, represented by his or her arterial and PA waveforms. Because of this narrowed pulse pressure, providers should ensure that mean arterial pressures are at least 65 mm Hg to maintain end-organ perfusion, rather than focusing on systolic or diastolic pressures. A potential negative effect that this nonpulsatile flow may have is decreased kidney and brain function, as the renal and neurological systems are sensitive to pulsatile blood flow. The nurse should monitor urine output, blood urea nitrogen, and creatinine levels to assess kidney function and perform neurological examinations to assess for any changes while the patient is receiving ECMO. If a patient’s cardiac function begins to improve and ECMO flows are decreased, his or her pulsatility may return.

A complication nurses may witness in a patient who is receiving VA ECMO is LV stun. This phenomenon is caused by inadequate ejection of the LV, exacerbated by the high afterload induced by the ECMO arterial cannula pressurizing the aorta. This process results in overdistention within the ventricle, which can lead to further myocardial damage and acute pulmonary edema and
can result in formation of clots in the LV. Signs of this phenomenon include a flat pulse pressure, increased PA pressure and PAOP, decreased LV wall motion and aortic valve standstill seen on echocardiogram, and pulmonary hemorrhage. If the patient can hemodynamically tolerate it, ECMO flows should be turned down to reduce the LV afterload to a goal pulse pressure greater than 10 mm Hg to promote opening of the aortic valve. Alternatively, afterload-reducing medications can be implemented. If LV stun does not resolve, other mechanical venting measures such as an additional cannula into the PA, LA, or LV, an Impella LV support device, or an IABP may be needed to decompress, or “vent,” the LV.26,28,29

Oxygen saturation levels, as well as arterial blood gas concentrations, should be measured from the patient’s right arm to identify adequate myocardial and cerebral perfusion and prevent falsely high interpretations of elevated saturation that may occur with measurements from the left arm or lower extremities. This phenomenon, referred to as North-South syndrome, can occur in peripherally cannulated patients when their native cardiac function begins to return but their lungs continue to be compromised. Because of the return of spontaneous circulation, the ECMO flows become unable to overcome the patient’s native CO to deliver well-oxygenated blood to the vessels of the aortic arch, which include coronary and cerebral circulations. Instead, the patient’s native CO will begin to pump deoxygenated blood from poorly functioning lungs to those vessels, which also supply the right arm, causing upper-body hypoxemia. The rationale for monitoring the patient’s oxygen saturation and blood gases from the right arm is to accurately reflect what the brain and the heart are receiving to avoid ischemic events. The well-oxygenated blood ends up circulating only in the lower half of the patient’s body, which can cause the falsely high interpretation of a patient’s oxygenation status.26,28

Interventions include increasing flows, increasing the venoarterial ECMO is considered an emergency until support can be reinstated. A mechanical complication while receiving ECMO flows and sweep can be gradually reduced and the patient maintains stable hemodynamics and adequate oxygenation while receiving minimal vasoactive agents and ventilator settings.27,28

Venovenous Indications

Venovenous ECMO is used for acute severe respiratory failure, most often in patients with acute lung injury and acute respiratory distress syndrome. Extracorporeal membrane oxygenation allows their lungs to rest on non-injurious ventilator settings while providing gas exchange for them within the circuit. Extracorporeal membrane oxygenation is indicated in most instances in the presence of venous inflow cannulas range from 21 to 25 French and arterial outflow cannulas from 15 to 21 French. Because the amount of pump flow is determined by the size of the cannulas, most operators favor placing the largest cannula possible. This may lead to limb ischemia by causing arterial obstruction. For this reason, antegrade perfusion sheaths are commonly inserted into the superficial femoral artery and connected to the arterial outflow cannula to provide oxygenated blood to the cannulated limb. Close monitoring of distal-extremity perfusion is of paramount importance to improve clinical outcomes among VA ECMO recipients.25

When a mechanical complication occurs such as clots or air in the circuit, oxygenator or pump malfunction, tubing rupture, or accidental decannulation, it is considered an emergency and the patient will be temporarily removed from ECMO until support can be reinstated. The nurse can expect to start or increase vasopressors, increase ventilator settings, and, in some circumstances, provide CPR while the circuit components are being changed out.27

Measuring cardiac recovery and readiness for decannulation in these patients involves performing an echocardiogram. Echocardiographic monitoring is done once ECMO flows and sweep can be gradually reduced and the patient maintains stable hemodynamics and adequate oxygenation while receiving minimal vasoactive agents and ventilator settings.27,28
of an 80% mortality risk, a ratio of partial pressure of arterial oxygen to fraction of inspired oxygen (FiO₂) of less than 80, and/or a Murray score of 3 to 4 from the previously mentioned lung failure. Other considerations when evaluating patients for VV ECMO are length of time receiving mechanical ventilator support, age, comorbidities and preexisting conditions, and likelihood of bridge to lung transplant.

**Venovenous Mechanics**

Cannula selection and placement are crucial elements in ECMO, which enable maximum support to be provided to the patient. In VV ECMO, cannulation techniques can include 2 sites (bilateral femoral veins, or femoral vein and RIJV) or a single site using a double-lumen cannula (DLC). With use of a DLC, the pump draws blood into the circuit in the inferior vena cava and/or superior vena cava, the blood flows into the oxygenator, and finally the oxygenated blood is delivered back to the patient through a cannula positioned at the RA to point toward the tricuspid valve.

**Venovenous Nursing Considerations**

Extracorporeal membrane oxygenation flow is increased to the maximum amount that can be achieved without causing significant recirculation of oxygenated blood. Because of the mixing of deoxygenated blood within the native lungs, adequate VV ECMO support is achieved when arterial oxygen saturation (Sao₂) is greater than 85%. Instead of focusing solely on Sao₂, the nurse should assess the heart rate, blood pressure, ability to wean off vasopressors, lactate levels, and urine output as indicators of adequate tissue perfusion.

To achieve the above-mentioned Sao₂ level, patients are placed on resting ventilator settings, which most often are represented by a positive end-expiratory pressure setting of 10 mm Hg, a low respiratory rate, and the lowest FiO₂ possible. The resting ventilator settings help to keep inspiratory pressure below 30 mm Hg, which can minimize further trauma to the lung. Although the VV ECMO circuit can supply adequate gas exchange to the patient, oxygen delivery depends on the patient’s native CO and hemoglobin level. Education and awareness regarding oxygen content and delivery are imperative in patients receiving VV ECMO to circumvent requests to increase resting ventilator settings. Venovenous ECMO provides no hemodynamic support to the patient. Pharmacological support, such as vasopressors, may be needed to augment hemodynamic demands. In addition, patients who suffer a cardiac arrest while receiving VV ECMO will require CPR. Minimal sedation is encouraged, as ambulation of VV ECMO patients is possible with the single DLC. If necessary, tracheostomy can help with ventilator weaning and may lower the amount of required sedation.

Recirculation on ECMO is defined as the pulling back of a portion of oxygenated blood into the ECMO circuit immediately after it is infused to the patient from the ECMO circuit. All patients receiving VV ECMO have some portion of blood being recirculated, as the inflow and outflow cannulas both lie in the venous system. Clinical signs of recirculation are a decrease in Sao₂, an increase in venous oxygen saturation, the presence of bright red, well-oxygenated blood within the venous catheter of the circuit, and hemodynamic responses to hypoxia.

Patients receiving VV ECMO are ready for decannulation when the sweep to the oxygenator can be shut off and the patient’s own lungs demonstrate effective gas exchange as evidenced by arterial blood gas values. Because of the absence of hemodynamic support, VV ECMO will not deliver oxygen to the same extent as VA ECMO will. However, with minimal recirculation and a suitable native CO, the patient will receive sufficient ECMO support for adequate oxygenation of end organs and tissues.

**Conclusion**

Acute mechanical circulatory support devices are becoming more widely used in the intensive care environment to help achieve higher levels of hemodynamic support than can be accomplished by using pharmacological interventions alone. Although these devices vary, critical care nurses should begin to develop expertise with them by becoming familiar with their anatomical placement, mechanics, hemodynamic response, and potential complications.

Because of the complexity of caring for patients with AMCS devices, it is vital that nurses receive additional training to obtain a strong understanding of hemodynamics so that they can accurately assess subtle or sudden changes and intervene as appropriate. Advanced assessment and analytical skills will help nurses provide safe care for these patients.

Financial Disclosures

Navin K. Kapur has received research grants and consulting and/or speaker honoraria from Abbott, Abiomed, Boston Scientific, Medtronic, Maquet, CardioAssist, and MD Start.

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